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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/416,902	10/13/1999	JOHN MCCAFFERTY	05569.0004.DVUS06	6750
22930	7590	02/03/2009		
HOWREY LLP - East C/O IP DOCKETING DEPARTMENT 2941 FAIRVIEW PARK DR, SUITE 200 FALLS CHURCH, VA 22042-2924			EXAMINER STEELE, AMBER D	
			ART UNIT	PAPER NUMBER
			1639	
			MAIL DATE	DELIVERY MODE
			02/03/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/416,902	<b>Applicant(s)</b> MCCAFFERTY ET AL.	
	<b>Examiner</b> AMBER D. STEELE	<b>Art Unit</b> 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on October 23, 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 44, 47, 48 and 53-62 is/are pending in the application.
- 4a) Of the above claim(s) 53-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 44, 47-48, 61-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/23/08</u>  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

1. New claims 61-62 were added and claims 46 and 51-52 were canceled by the amendment filed on November 30, 2005.

The amendment to the claims received on April 2, 2007 amended claim 44 and canceled claim 45.

The supplemental amendment received on June 6, 2007 amended claim 44.

The amendment to the claims received on November 16, 2007 canceled claims 49-50.

The amendment to the claims received on October 23, 2008 amended claims 44, 47-48, and 61-62 and canceled claims 53-60.

Claims 44, 47-48, and 61-62 are currently pending and under consideration.

### ***Priority***

2. The present application claims status as a divisional of 08/484,893 filed June 7, 1995 (now U.S. Patent 6,172,197), which is continuation of 07/971,857 filed January 8, 1993 (now U.S. Patent 5,969,108), which is a continuation of PCT/GB91/01134 filed July 10, 1991.

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) for UK 9015198.6 filed July 10, 1990; UK 9022845.3 filed October 19, 1990; and UK 9024503.6 filed November 12, 1990. The certified copies have been filed in parent Application No. 07/971,857, filed on January 8, 1993.

***Information Disclosure Statement***

4. The information disclosure statement (IDS) submitted on October 23, 2008 is being considered by the examiner.

**Withdrawn Objections**

5. The objections to claims 44, 47-48, and 61-62 are withdrawn in view of the claim amendments received on October 23, 2008.

**Withdrawn Rejections**

6. The rejection of claims 44, 47-48, and 61-62 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,555,313 is withdrawn in view of the terminal disclaimer filed on October 23, 2008.

7. The rejection of claims 44, 47-48, and 61-62 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-41 of U.S. Patent No. 5,885,793 is withdrawn in view of the terminal disclaimer filed on October 23, 2008.

8. In addition, applicants have also filed terminal disclaimers for U.S. Patent Nos: 7,195,866; 6,916,605; 6,582,915; 6,544,731; 6,521,404; 5,871,907; 5,858,657; and 5,837,242 which were proposed in the PTO-90C (i.e. supplemental communication) mailed on September 22, 2008.

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### New Rejection

#### *Double Patenting*

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 44, 47-48, and 61-62 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,017,732. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed invention and the invention as claimed in U.S. Patent 6,017,732 are drawn to methods of making specific binding pairs (sbp).

For claims 44, 47-48, and 61-62, U.S. Patent No. 6,017,732 claims methods comprising (a) providing a population of mutated nucleic acid molecules encoding sbp wherein sbp are VH and VL (i.e. Fab), (b) producing a population of bacteriophage displaying on the surface sbps, (c) selection of a sbp via binding (i.e. contacting and separating), etc. (see claims 1-25). In addition,

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the specification defines bacteriophage as filamentous bacteriophage (see column 5, line 19 and column 6, line 45).

### ***Arguments and Response***

11. Applicants contend that since U.S. Patent 6,017,732 is assigned to the Medical Research Council (MRC) only and not to the MRC and Cambridge Antibody Technology, Inc., a terminal disclaimer is not available to obviate a possible non-statutory double patenting rejection.

However, an assignee for the present application is not of record. In addition, terminal disclaimers may be required by an owner in whole or in part (i.e. common assignee, common inventor). See 37 CFR 1.321 and MPEP § 804.

### ***Future Communications***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMBER D. STEELE whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/  
Patent Examiner, Art Unit 1639

January 30, 2009